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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,593	11/02/2006	Pierre Andreoletti	BJS-571-23	4378

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

HORNING, MICHELLE S

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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03/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,593	Applicant(s) ANDREOLETTI ET AL.	
	Examiner MICHELLE HORNING	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8 and 11-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/3/2007, 2/4/2005</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> . |

DETAILED ACTION

This office action is responsive to communication filed 2/12/2009. Given the rejections below, no additional species were searched.

It is noted that a request under Rule 48 was filed for the correction of inventorship, although it appears that it was meant to be under Rule 47. This is rendered moot in view of the updated oath filed 1/10/2007.

Election/Restrictions

Applicant's election of Group I in the reply filed on 2/12/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The elected species are C4bp, CD21 ligand (C3d) and HBsAg. Note that Applicant provides that claims 1-3, 6, 7, 9 and 10 read upon the elected species.

Information Disclosure Statement

The Information Disclosure Statements have been considered in its entirety.

Drawings

The drawings are objected to because Figure 1 or its corresponding figure legend fails to provide sequence identifiers; see MPEP 2422.02. Note that the inclusion of sequence identifiers in the description of the drawings would rectify this

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objection without submission of new drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 6, 7 and 9 are objected to because of the following informalities: they depend from withdrawn claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO/2000/069907 (Hill).

Hill describes a C-terminal fragment of C4bp which leads to spontaneous multimerization (p. 1-2). Note that this meets the limitation of a C4bp core and a scaffold as defined by the instant specification (p. 4 and 9). The authors also provide that "the invention may be exploited by incorporating an adjuvant on the scaffold, together with the immunogen. Suitable adjuvants are, for example, bacterial toxins and cytokines, such as interleukins" (p. 14). Hill describes using a heterologous polypeptide that is heterologous to the protein scaffold, including an antigen (p. 9-10). Different pharmaceutical carriers are described on p. 29, including water and liquid polyethylene glycol.

Claims 1, 2, 3, 6, 7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6238670 (Fearon) as further evidenced by Netter et al (2001).

Fearon describes a composition comprising an antigen linked to a ligand for CD21 (see whole document). Column 2 provides that coupling C3d to an immunogen of

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interest enables modulation of the immune response to the immunogen. Further, the authors describe that the immune response may be enhanced by coupling a plurality of C3d molecules. Columns 5 and 6 provide the following recitation: "The carrier structure may be any vaccine or biological particle for administration, for example in the membrane or on the surface of a virus, on HBsAg particles and so on. Coexpression of the antigen/immunogen and ligand for CD21 or CD19 may follow incorporation of appropriate nucleic acid into the viral genome." Note that p. 6 of the instant specification provides that the first and third component may be the same molecule. Thus, an HBsAg may be both a scaffold protein and an antigen. Column 7 provides that the described invention may contain a pharmaceutically acceptable excipient. Note that HBsAg is considered both a scaffold and an antigen in the above teaching. Further, given the reference only provides a conjugate of two elements, the structural limitations of Claim 9 are met and thus, functionally, they must lead to the same effect.

In support of the teachings by Fearon above, Netter describes HBsAg-S as having the capacity to self-assemble into empty envelope particles and that one particle contains about 100 molecules (p. 2130-1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648